

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 401129GA ✓	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DE00/02758 ✓	International filing date (day/month/year) 12 August 2000 (12.08.00) ✓	Priority date (day/month/year) 16 August 1999 (16.08.99) ✓	
International Patent Classification (IPC) or national classification and IPC G01N 33/543, C12Q 1/68			
Applicant NOVEMBER AKTIENGESELLSCHAFT GESELLSCHAFT FÜR MOLEKULARE MEDIZIN			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 24 February 2001 (24.02.01)	Date of completion of this report 20 November 2001 (20.11.2001)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE00/02758

I. Basis of the report

1. With regard to the elements of the international application:*

the international application as originally filed

the description:

pages _____ 1-6 _____, as originally filed
 pages _____ _____, filed with the demand
 pages _____, filed with the letter of _____

the claims:

pages _____ 11,12 _____, as originally filed
 pages _____ _____, as amended (together with any statement under Article 19
 pages _____ _____, filed with the demand
 pages _____ 1-10 _____, filed with the letter of 22 October 2001 (22.10.2001)

the drawings:

pages _____ _____, as originally filed
 pages _____ _____, filed with the demand
 pages _____, filed with the letter of _____

the sequence listing part of the description:

pages _____ _____, as originally filed
 pages _____ _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
 the language of publication of the international application (under Rule 48.3(b)).
 the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in written form.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority in written form.
 furnished subsequently to this Authority in computer readable form.
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

the description, pages _____
 the claims, Nos. _____
 the drawings, sheets/fig. _____

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/DE 00/02758

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims	1-10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1 = WO-A-98/31839;

D2 = EP-A-0 244 326;

D3 = US-A-5 567 301;

D4 = WO-A-98/19153.

1. Independent Claims 1 and 6 were made more precise by inclusion of the feature that promoters of conductivity are introduced **into** the biopolymer layer to increase the conductive capacity.
 - 1.1. The description makes clear that this occurs prior to or after hybridization (i.e., after completion of sensitization), e.g., through dampening, electrochemical dispersion, addition of electroactive substances that specifically bond to ssDNA or dsDNA, etc. (see the third paragraph on each of pages 4 and 5).
 - 1.2. D1 is considered to be the closest prior art.
 - (i) D1 discloses two essentially different methods and/or devices. A first embodiment involves

hybridization of two nucleic acid species immobilized on planar surfaces. The single-strand nucleic acids are immobilized on the sensor surface by means of conventional alkylthiol substituents. The gold atoms involved in the bonding are integral to the electrode surface and thus not considered to be part of the biopolymer layer.

(ii) D1 discloses as the second embodiment the immobilization of protein ligands using polyhistidine and a spacer-linked metal ion, i.e., here, the metal ion is integral to the biopolymer layer. This embodiment, however, uses only an immobilized scavenger species (the analyte is in solution), in addition, the measurement sensor is not configured as a planar surface (Figures 14, 15).

None of the above-mentioned embodiments prejudices the novelty of the claimed method or device.

- 1.3 The prior art documents D2-D4 differ from the claimed subject matter in that no second biopolymer layer bonded to a planar solid phase is provided. Furthermore, D2 and D4 do not disclose the dispersion of promoters of conductivity in the biopolymer layer.
- 1.4. The subject matter of Claims 1-10 is thus novel under PCT Article 33(2).
- 1.5 The examination of Claim 6 for novelty is based on the inclusion of all the technical features listed in this claim. Should the claim be amended in the

sense that the second sensitized surface as an analyte (e.g., a marking chip) is not a component of the actual sensor device, a problem with novelty would arise with respect to the prior art according to D1 and D3.

Both documents disclose sensor devices in which metal ions and atoms are present in the biopolymer layer (see 1.2(ii) and D3, Figure 1, column 4, line 61 to column 5, line 8). These inherently contribute to an increase in conductivity.

2. Introducing promoters of conductivity into biopolymer layer(s) in conductometric devices based on an interaction between two sensitized, planar surfaces is not suggested by the relevant prior art.

Therefore, the subject matter of Claims 1-10 is considered to be inventive under PCT Article 33(3).

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

3. Contrary to PCT Rule 5.1(a)(ii), the description does not cite documents D1-D4 or indicate the relevant prior art disclosed therein.
4. The description is not consistent with the claims (PCT Rule 5.1(a)(iii)).